# In the United States Court of Federal Claims

No. 15-362V
Filed Under Seal: April 1, 2019
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| BRYAN MACIEL,<br><br>Petitioner,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | ) | National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–1 to –34; Multiple Sclerosis; Human Papillomavirus Vaccine; Significant Aggravation; Optic Neuritis. |

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**MEMORANDUM OPINION AND ORDER**

GRIGGSBY, Judge

## I. INTRODUCTION

Petitioner, Bryan Maciel, seeks review of the October 12, 2018, Decision of the special master (the "October 12, 2018, Decision") denying his claim for compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa–1 to –34. For the reasons set forth below, the Court (1) **DENIES** petitioner's motion for review and (2) **SUSTAINS** the decision of the special master.

* This Memorandum Opinion and Order was originally filed under seal on April 1, 2019 (docket entry no. 50). In the Memorandum Opinion and Order, the Court ordered the parties to file a joint status report advising the Court of their views with respect to what information, if any, should be redacted, on or before May 1, 2019. The parties did not file a joint status report requesting any redactions. And so, the Court reissues the Memorandum Opinion and Order, dated April 1, 2019, without any redactions.

## II. FACTUAL AND PROCEDURAL BACKGROUND[1]

### A. Factual Background

In this Vaccine Act matter, petitioner, Bryan Maciel, alleges that he suffered optic neuritis and multiple sclerosis ("MS") as a result of receiving the human papillomavirus vaccine ("HPV") on August 28, 2013; October 13, 2013; and March 6, 2014; and that the March 6, 2014 dose of HPV significantly aggravated his underlying MS. *See generally* Pet. Mot. On October 12, 2018, the special master denied petitioner's claim for compensation. *See generally Maciel v. Sec'y of Health & Human Servs.*, No. 15-362V, 2018 WL 6259230 (Fed. Cl. Spec. Mstr. October 12, 2018). In his motion for review, petitioner requests that the Court: (1) set aside the special master's decision; (2) grant his claim for compensation; or (3) remand this matter to the special master. Pet. Mot. at 2.

#### 1. Petitioner's Medical History

Petitioner's medical history is discussed in detail in the special master's October 12, 2018, Decision and is summarized here. *See generally id.* On August 28, 2013, petitioner received his first dose of HPV, at the age of thirteen. Pet. Ex. 7 at 45; Pet. Ex. 15 at 4-5. Petitioner subsequently received two additional doses of HPV on October 30, 2013, and March 6, 2014, respectively. Pet. Ex. 7 at 42-44; Pet. Ex. 15 at 2-3.

Prior to receiving the first dose of HPV, petitioner was relatively healthy, notwithstanding common ailments, and he had no history of neurologic symptoms prior to completing the HPV series. *See, e.g.*, *Maciel*, 2018 WL 6259230, at *1; Pet. Ex. 9 at 6. No adverse reactions or complaints were noted at the time that petitioner received the first two doses of HPV. Pet. Ex. 1 at 1.

On March 8, 2014, two days following the receipt of the third dose of HPV, petitioner presented to the West Boca Medical Center emergency room located in Boca Raton, Florida with intermittent blurred vision in his left eye and a headache. Pet. Ex. 14 at 107, 114, 118. At the

[1] The facts recounted in this Memorandum Opinion and Order are taken from the petitioner's petition ("Pet."); petitioner's motion for review ("Pet. Mot."); petitioner's exhibits ("Pet. Ex."); and the special master's October 12, 2018, Decision ("Decision"). Except where otherwise noted, the facts recited herein are undisputed.

time, petitioner reported that the onset of these symptoms began one week prior. *Id.* at 114 ("patient has intermittent left blurred vision, sometimes related with headache . . . since the last week"). The attending physician, Dr. Luis Rios, noted diminished acuity in petitioner's left eye, but no recent infection. *Id.* A computerized tomography ("CT") scan also revealed no acute intracranial abnormalities. *Id.* at 135-36. And so, after receiving an ophthalmologic exam and diagnosis of an ocular migraine, petitioner was discharged and directed to follow-up the next day if his symptoms did not improve. *Id.* at 112, 122.

On March 9, 2014, petitioner returned to the emergency room with complaints of persistent blurred vision in his left eye and accompanying headaches. *Id.* 14 at 62-65. An ophthalmologic exam revealed decreased visual acuity of 20/200 in the left eye. *Id.* at 64. A magnetic resonance imaging ("MRI") also revealed multiple white matter lesions in the cerebral hemisphere and left cerebellar peduncle, as well as a suspected lesion on the anterior left optic nerve. *Id.* at 98. Petitioner's medical records show that the larger lesion showed "very faint gadolinium enhancement" and a potential "faint area of enhancement" in the anterior left optic nerve. *Id.* And so, petitioner's neurologist suspected MS and recommended that petitioner be transferred to the Miami Children's Hospital for further treatment. *Id.*

After petitioner arrived at the Miami Children's Hospital, the treating physician, Dr. Ann Hyslop, noted that petitioner's symptoms were part of the same progressive course of an ocular migraine. *See id.* at 114-15. An MRI performed at Miami Children's Hospital revealed "[d]iffuse bilateral hemispheric areas of signal abnormality" in the white matter, along with "[s]ignal abnormality and abnormal enhancement" in the left optic nerve. Pet. Ex. 13 at 153. A lumbar puncture and subsequent cerebrospinal fluid ("CSF") analysis also revealed "[a]ll evoked" oligoclonal bands, which physicians deemed to be consistent with an MS diagnosis. *Id.* at 11, 129-31; Pet. Ex. 7 at 10. At the time of petitioner's discharge on March 13, 2014, his medical record noted that the test results supported a diagnosis of MS, along with retrobulbar optic neuritis in the left eye. Pet. Ex. 13 at 11-12, 107.

On March 14, 2014, petitioner presented to Dr. Roberto Lopez-Alberola, a physician with the neurology department at the University of Miami Miller School of Medicine, for further treatment. *See generally* Pet. Ex. 5. Dr. Roberto Lopez-Alberola found petitioner to be

improving, but still experiencing left eye blurriness. *Id.* at 11. After a review of petitioner's medical history, Dr. Lopez-Alberola concluded that the differential diagnosis for petitioner was neuromyelitis optica. *Id.*

On March 15, 2014, petitioner was admitted to the Jackson Health Systems' emergency room with complaints of additional worsening symptoms, including stomach pain, nausea, vomiting, and numbness and tingling in his left leg. Pet. Ex. 10 at 23. Petitioner was evaluated by a neuro-ophthalmologist, Dr. Sean Gratton, who opined that petitioner likely had MS with accompanying optic neuritis. *Id.* at 28. A repeat MRI also revealed several non-enhancing lesions, which were noted to be consistent with an ongoing and preexisting demyelinating process suggestive of MS and a possible arachnoid cyst. *Id.* 10 at 34.

On March 20, 2014, petitioner presented for a repeat MRI to evaluate his optic nerves. Pet. Ex. 8 at 58. The MRI did not identify intraorbital mass lesions and no abnormal enhancement or edemas along the bilateral optic nerve were noted. *Id.* A subsequent thoracic MRI conducted on March 21, 2014, revealed spinal fluid collection between T1 and T2 signals that were thought to be consistent with an arachnoid cyst. *Id.* at 56; Pet. Ex. 10 at 39-40.

On March 28, 2014, petitioner presented to Dr. Lopez-Alberola for a neurology follow-up, and the treatment notes from this visit indicate that petitioner had experienced no new symptoms since his discharge from the Jackson Health Systems. Pet. Ex. 5 at 8-9. And so, Dr. Lopez-Alberola determined that the results of petitioner's most recent MRI were consistent with a diagnosis of probable MS. *Id.* at 9.

On March 31, 2014, petitioner presented to Dr. Byron Lam, a neuro-ophthalmologist, for evaluation. Pet. Ex. 8 at 30-33. An examination conducted by Dr. Lam revealed that petitioner continued to experience decreased visual acuity in the left eye. *Id.* at 30-31. And so, Dr. Lam concluded that petitioner's symptoms were consistent with an onset of optic neuritis. *Id.* at 33.

On May 10, 2014, approximately one month after petitioner received his third dose of HPV, petitioner was admitted to the hospital for a third time for treatment of an MS flare that caused blurred vision in his left eye and tingling in his hands and feet. Pet. Ex. 10 at 45-46. At

that time, petitioner received additional rounds of solu-medrol steroid therapy, and he was discharged on May 15, 2014, with a diagnosis of an MS flare. *Id.* at 45-47.

On September 18, 2014, petitioner's mother, Kelly Maciel mentioned to petitioner's primary care physician, Dr. Renato Berger, concerns that the HPV vaccinations could have caused petitioner's MS. Pet. Ex. 7 at 34. Dr. Berger's contemporaneous treatment notes do not reflect that he expressed an opinion regarding Mrs. Maciel's concerns. *Id.*

On November 11, 2014, petitioner returned to see Dr. Lam for a follow-up appointment concerning his optic neuritis course of treatment. Pet. Ex. 8 at 8. The treatment notes from that visit indicate that petitioner's MS improved since his MS flare in May 2014, but petitioner still experienced decreased vision in his left eye. *Id.* On April 10, 2015, petitioner's parents filed a petition seeking compensation on behalf of petitioner under the Vaccine Act. *See generally* Pet.

**2. Proceedings Before The Special Master**

Petitioner's parents, Elias and Kelly Maciel, commenced this Vaccine Act case on behalf of their son on April 10, 2015. *Id.* at 1.

On April 21, 2016, petitioner submitted an expert report by Dr. Carl Tornatore, in which Dr. Tornatore opined that petitioner's third dose of HPV resulted in an episode of optic neuritis that was subsequently diagnosed as MS. Pet. Ex. 16 at 9. Dr. Tornatore also opined that it was possible that petitioner experienced a significant aggravation of his optic neuritis and MS, because the third dose of HPV was administered during an MS attack. *Id.* And so, Dr. Tornatore concluded that, but for the third dose of HPV, petitioner would not have developed MS. *Id.*

On October 14, 2016, the Secretary of Health and Human Services ("Secretary") submitted an expert report by Dr. Adil Javed opining that: (1) petitioner had MS prior to receiving the third dose of HPV; (2) there is no scientific certainty that HPV can trigger MS; and (3) a causal relationship between HPV and MS is merely hypothetical. *See generally* Resp't. Ex. A. Dr. Javed also opined that petitioner's condition proceeded as would be expected in any MS case presenting with optic neuritis, because MS symptoms may fluctuate throughout the period of onset and recovery. *Id.* at 12. And so, Dr. Javed concluded that HPV neither caused petitioner's MS, nor significantly aggravated this disease. *Id.* at 13.

On January 11, 2017, petitioner submitted a supplemental expert report by Dr. Tornatore which responded to the findings of Dr. Javed. *See generally* Pet. Ex. 26. In the supplemental expert report, Dr. Tornatore opined that it was biologically plausible that HPV induced an autoimmune nervous system injury, because petitioner's symptoms changed after receiving HPV and vaccines can exacerbate MS flares. *Id.* at 4. And so, Dr. Tornatore concluded that the third dose of HPV that petitioner received caused an episode of optic neuritis—the initial event in what was subsequently diagnosed as MS. *Id.*

On April 21, 2017, the Secretary submitted a supplemental expert report by Dr. Javed. *See generally* Resp't. Ex. B. In the supplemental expert report, Dr. Javed opined that HPV did not cause petitioner's MS, because an MRI report mentioned non-enhancing lesions—which are chronic and support the presence of MS—prior to the date on which petitioner received the third dose of HPV. *Id.* at 2. Dr. Javed also observed that petitioner's progress report from August 26, 2014, documented remarkable improvement in the left eye as expected from an episode of optic neuritis related to MS. *Id.* at 3. And so, Dr. Javed concluded that petitioner had MS prior to receiving the third dose of HPV and that any relapse that petitioner experienced followed the natural course of the disease without any alteration due to HPV. *Id.* at 5.

Petitioner also submitted two affidavits in support of his claim. In these affidavits, petitioner's parents detail their recollections of petitioner's symptoms after receiving HPV and confirm that petitioner began experiencing symptoms "within hours" of receiving his third dose of HPV. Pet. at 3-6. The Maciels also state in the affidavits that petitioner experienced adverse symptoms prior to March 6, 2014—the date on which petitioner received the third dose of HPV—and the Maciels attribute the onset of petitioner's intermittent headaches to the second dose of HPV. Pet. 3,6.

In addition, both parties filed medical and scientific literature in this case. In this regard, petitioner submitted eight medical articles in support of his petition.[2]

[2] The petitioner submitted the following medical articles: (1) *Multiple Sclerosis: Deeper Understanding of Its Pathogenesis Reveals New Targets for Therapy*, by L. Steinman, et al., which provides an outline of the typical course of MS; (2) *The Use of Vaccinations in Patients with Multiple Sclerosis*, by D. Jefferey, which questions the propriety of administering vaccines to MS patients; (3) *Vaccinations: Special Considerations*, by the National Multiple Sclerosis Society, which questions the medical wisdom of

The Secretary also submitted six medical articles.[3]

On March 22, 2018, the special master held an entitlement hearing on petitioner's claims. *See generally* Tr. During the entitlement hearing, Dr. Tornatore testified that petitioner suffered from pre-existing MS, which was significantly aggravated by petitioner's receipt of the third dose of HPV on March 6, 2014. *Id.* at 18. Specifically, Dr. Tornatore testified that the third dose of HPV induced a significant aggravation of petitioner's MS because the vaccine was administered during an MS attack. *Id.* In this regard, Dr. Tornatore opined that, although

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vaccinating MS patients during a relapse; (4) *Molecular Mimicry, Microbial Infection, and Autoimmune Disease: Evolution of the Concept*, by M.B.A. Oldstone, which focuses on understanding the sequence of events that lead to pathological effects and ways to prevent the autoimmune destructive process; (5) *Acute Disseminated Encephalomyelitis: Clinical and Pathogenesis Features*, by Farshid Noorbakhsh, et al., which discusses how minor neuropsychologic abnormalities have been reported in pediatric cases years after the disease even if the imaging profile is normal; (6) *A very high level of crossreactivity is an essential feature of the T-cell receptor*, by Don Mason, which asserts that microbiological antigens from a bacteria or virus could activate T cell receptor, causing an autoimmune response in the nervous system; (7) *Clinical/Scientific Notes on Neuromyelitis Optica Following Human Papillomavirus Vaccination*, by Til Mege, MD, et al., which discusses the possibility of Neuromyelitis Optica being caused by HPV; and (8) *Immunologic Mechanisms in Multiple Sclerosis; Exacerbation by Type A Hepatitis and Skin Test Antigens*, by Robert Owen, MD, et al., which describes successive exacerbations of MS following a hepatitis A infection and suggests that an immune pathogenesis for both exacerbations of MS and clinical manifestation of infection with hepatitis A virus. *See generally* Pet. Exs. 18-25.

[3] The Secretary submitted the following medical articles: (1) *Risk of Autoimmune Diseases, and Human Papilloma Virus (HPV) Vaccines: Six Years of Case Referent Surveillance*, by L. Grimaldi-Bensouda, et al., which presents a case study conducted with HPV and autoimmune diseases, including MS, where exposure to HPV was not associated with an increased risk of autoimmune diseases; (2) *Human Papillomavirus Vaccination and Risk of Autoimmune Disease: A Large Cohort Study of Over 2 Million Young Girls in France*, by S.Miranda, et al., which presents a case study showing that there is no heightened risk regarding the risk of autoimmune diseases after HPV; (3) *Quadrivalent HPV Vaccination and Risk of Multiple Sclerosis and Other Demyelinating Diseases of the Central Nervous System*, by N. M. Scheller, et al., which presents a case study of two Scandinavian countries, finding that HPV among girls and women is not associated with the development of MS or other demyelinating diseases; (4) *Surveillance of Autoimmune Conditions Following Routine Use of Quadrivalent Human Papillomavirus Vaccine*, by C. Chao, et al., which presents findings from an autoimmune surveillance where no cluster of disease onset in relation to vaccination timing was found for any auto-immune condition; (5) *International Pediatric Multiple Sclerosis Study Group Criteria for Pediatric Multiple Sclerosis and Immune-Mediated Central Nervous System Demyelinating Disorders: Revisions to the 2007 Definitions*, by L.B. Krupp, et al., which provides an updated definition of neuromyelitis optica to better delineate its presence in children; and (6) *Molecular Mimicry, in Adverse Effects of Vaccines: Evidence of Causality*, by the Institute of Medicine, which notes the difficulty in proving that a particular human autoimmune disease is due to molecular mimicry and the sequence homology between a foreign antigen and self-antigen leading to the development of pathologic damage and disease. *See generally* Resp't. Exs. C-H.

petitioner appeared healthy at the time of vaccination, petitioner likely had some "baseline inflammation" that could remain asymptomatic. *Id.* at 42. And so, Dr. Tornatore concluded that that HPV augmented underlying inflammation already present, causing a more robust, systematic inflammatory response. *Id.* at 60. Given this, Dr. Tornatore also concluded that petitioner would have remained symptom free and that any underlying inflammation would have resolved on its own in four to six weeks, but for petitioner's receipt of the third dose of HPV. *Id.* at 31.

During the entitlement hearing, Dr. Javed testified that the onset of petitioner's MS/optic neuritis predated the administration of the third dose of HPV, and that petitioner's pre-vaccination symptoms proceeded as expected with any MS case presenting optic neuritis. *Id.* at 113, 118, 150. Dr. Javed also testified that a pediatric case of optic neuritis would not completely resolve within days and then immediately recur after a vaccination. *Id.* 108-10. In addition, Dr. Javed acknowledged that HPV could exacerbate MS. *Id.* at 146-47. But, he opined that an inactivated vaccine, like HPV, is not likely to promote inflammation. *Id.* Given this, Dr. Javed opined that it was improbable that HPV could exacerbate inflammation. *Id.* at 147. And so, Dr. Javed concluded that petitioner could not make a showing that his overall condition worsened because of the third dose of HPV. *Id.* at 150.

### 3. The Special Master's October 12, 2018, Decision

On October 12, 2018, the special master issued a decision denying petitioner's Vaccine Act claim. *See generally Maciel v. Sec'y of Health & Human Servs.*, No. 15-362V, 2018 WL 6259230 (Fed. Cl. Spec. Mstr. October 12, 2018). In the October 12, 2018, Decision, the special master considered, as a preliminary matter, the medical concepts relevant to MS and prior Vaccine Act cases in which a petitioner alleged that a vaccine significantly aggravated MS. *Id.* at *22-23. In this regard, the special master observed that "MS is categorized as a demyelinating central nervous system disease." *Id.* at *22. The special master also observed that patients diagnosed with MS typically experience multiple episodes of central nervous system ("CNS") demyelination that are separated in time and space, evidencing a more progressive decline in their overall health course. *Id.* And so, the special master recognized that the demyelination that results in MS is believed to be autoimmune in nature. *Id.* (Ex. A at 3; Tr. at 90:18 (providing Dr. Javed's characterization of MS as an autoimmune disease)).

The special master also observed that the parties' experts largely agree about the proper definition of MS and the kind of clinical or radiologic evidence required to establish this disease. *Id.* But, the special master further observed that the experts disagree to some extent about the typical course of optic neuritis and the disease's most likely resolution. *Id.* at *23. In this regard, the special master recognized that optic neuritis is defined as 'inflammation of the optic nerve.' *Id.* at *23. (quoting *Dorland's Illustrated Medical Dictionary* 1252 (32nd ed. 2012)). And so, the special master concluded that, a clinical diagnosis of optic neuritis is made based upon a patient's health history and clinical history; the symptoms of optic neuritis typically progress to a nadir over a period of hours to days; and recovery of visual acuity begins two to four weeks following onset. *Id.*

With regard to petitioner's claim that HPV caused petitioner's MS/optic neuritis, the special master determined that petitioner's causation claim lacked evidentiary support, because the evidence showed that petitioner's optic neuritis predated the March 6, 2014 dose of HPV. *Id.* at *24. In this regard, the special master found that Dr. Tornatore acknowledged during the entitlement hearing that it was reasonable to conclude from the medical record that petitioner's optic neuritis predated his receipt of the third dose of HPV on March 6, 2014. *Id.*; Tr. at 11:22-12:3, 47:19-47:25. And so, the special master concluded that the medical record "persuasively establish that [petitioner's] optic neuritis symptoms began pre-vaccination, around March 3, 2014." *Maciel*, 2018 WL 6259230, at *24.

With regards to the testimony of Dr. Tornatore, the special master also observed that "[o]verall I found him to be a competent and credible expert, with more than sufficient expertise on the topic of MS and interpretation of the radiologic evidence relevant to it to opine in this case." *Id.* at *28. But, the special master observed that Dr. Tornatore's "professional focus is not on immunologic matters." *Id.* And so, the special master concluded that Dr. Tornatore's "overall credibility and expertise on the topic of MS was not enough to imbue this sub-component of his testimony with the evidentiary heft needed to outweigh [the Secretary's] more robust, literature-supported contentions that HPV specifically is *unlikely* to contribute to the processes resulting in MS, cause a damaging flare, or worsen an existing flare to the degree necessary to significantly aggravate a course of MS." *Id.* (emphasis in original).

The special master also observed that neither of the parties' experts suggested that the prior two doses of HPV that petitioner received on August 28, 2013, and October 20, 2013, initiated petitioner's MS. *Id.* at *24. Given this, the special master found that, "the medical record best supports the conclusion that [p]etitioner's MS/optic neuritis began *before* [the] receipt of the third HPV dose on March 6, 2014—and was not caused by the earlier two doses either." *Id.* (emphasis in original). And so, the special master concluded that petitioner's direct causation claim could not succeed. *Id.*

With regards to petitioner's claim that the third dose of HPV significantly aggravated his MS/optic neuritis, the special master also determined that petitioner had not offered preponderant evidence to support a significant aggravation claim for three reasons. *Id.* at *25-26. First, the special master determined that petitioner's post-vaccination symptoms constituted a single MS flare that predated the receipt of the third dose of HPV, because the record evidence best establishes that petitioner's optic neuritis had not completely resolved by March 6, 2014. *Id.* at *25. The special master also observed that the evidence submitted by the Secretary in this case supported this conclusion. *Id.* Notably, the special master found that the Secretary "persuasively established that optic neuritis commonly does not resolve quickly, especially the pediatric version . . . ." *Id.* The special master also found that the medical literature submitted by the Secretary makes clear that optic neuritis progresses over hours to days, with recovery usually no sooner than two to four weeks after onset. *Id.* (citing Resp't Ex. A at 2). And so, the special master concluded that the Secretary persuasively established that individual MS flares generally last more than a few days—and that such flares are also usually separated in time by weeks or more before they are deemed to reflect a new flare. *Id.*; *see also* Resp't Ex. A at 6; *see generally* Tr. at 98:9-99:15, 104:3-104:14.

Second, the special master determined that the medical record in this case "provides many grounds" for viewing petitioner's optic neuritis as a single, initial MS flare, beginning on March 3, 2014. *Maciel*, 2018 WL 6259230, at *25. Notably, the special master found that the medical record suggests that petitioner's symptoms were broadly intermittent, both before and after the receipt of the third dose of HPV. *Id.* The special master also determined that it was significant that no medical provider viewed the petitioner's two headache incidents as distinct, rather than being part of the same progressive continuum. *Id.*; s*ee also* Pet. Ex. 13 at 114

("[s]ymptoms began on 3/3/14 intermittently and became progressively worse over the week"). Given this, the special master further determined that the period in which petitioner's symptoms were in remission was too short to draw the conclusion urged by Dr. Tornatore—that the third dose of HPV significantly aggravated petitioner's MS/optic neuritis. *Maciel*, 2018 WL 6259230, at *25. And so, the special master concluded that "all in all, the evidence suggests it is more likely than not that [p]etitioner's optic neuritis lasted longer than a few days and bridged the pre and post-vaccination period." *Id.*

Third, the special master determined that petitioner did not experience an overall worsening of his MS/optic neuritis after receipt of the third dose of HPV. *Id.* at *26. In this regard, the special master observed that this determination did not "preclude the conclusion that HPV could have worsened [petitioner's] overall MS/optic neuritis course *otherwise*—not by provoking a second flare, but instead by exacerbating the existing optic neuritis/initial MS flare." *Id.* (emphasis in original). But, the special master determined that petitioner did not demonstrate such a worsening of his condition, because "the medical record [did] not suggest that [petitioner's] MS/optic neuritis course was notably worse than what would be expected for an individual suffering from MS who received no vaccine." *Id.*

In addition, the special master determined that the medical record failed to corroborate petitioner's contention that he was experiencing a systemic immune response after receipt of the third dose of HPV, because the medical record "set[s] forth no documented occurrences of a reaction, nor any statements to treaters that [p]etitioner experienced a vaccine reaction." *Id.* The special master also determined that the Secretary "effectively rebutted Dr. Tornatore's arguments about the significance of eosinophil levels, [by establishing that:] (a) absolute eosinophil count matters more than the percentage level, (b) other testing that would reveal inflammation, like the ESR rate or CRP levels, was negative, and (c) eosinophilia is not otherwise deemed a marker of MS." *Id.* And so, the special master concluded that the medical record in this case was inconsistent with petitioner's contention that petitioner experienced a serious deterioration of his MS due to vaccination. *Id.*

Lastly, the special master determined that petitioner failed to establish a plausible causation theory that was supported by sufficient reliable evidence to show that HPV could

exacerbate an existing course of MS. *Id.* at *27. In this regard, the special master acknowledged that petitioner "did offer some reliable evidence in support of the 'can cause' element of his claim." *Id.* But, the special master determined that petitioner did not meet his burden to demonstrate—with reliable scientific or medical evidence—that HPV can worsen an individual's subsequent overall course of MS. *Id.*

Notably, the special master observed that "Dr. Tornatore did not relate in his testimony particularized observations from his own medical experience that would render [the contention that HPV can worsen MS] plausible." *Id.* The special master also observed that the Secretary "offered reliable scientific epidemiologic evidence directly relating to the HPV vaccine and MS, and suggesting the absence of a relationship." *Id.* (citing Resp't Ex. A at 10; Resp't Ex. C, D, F). Given this, the special master concluded that there was not enough reliable and persuasive evidence to find it plausible that HPV could significantly aggravate the overall course of MS. *Id.* And so, the special master concluded that petitioner has not carried his burden of proof and denied petitioner's significant aggravation claim. *Id.*

Petitioner, alleging error, seeks review of the special master's October 12, 2018, Decision. *See generally* Pet. Mot.

**B. Procedural Background**

Petitioner commenced this action on April 10, 2015. Pet. at 1. After the special master held an evidentiary hearing on March 22, 2018, the special master denied petitioner's claim on October 12, 2018. *Maciel*, 2018 WL 6259230, at *28.

Petitioner filed a motion for review of the special master's October 12, 2018, Decision on November 12, 2018. *See generally* Pet. Mot. On December 12, 2018, the Secretary filed a response and opposition to petitioner's motion for review. *See generally* Resp't. Resp.

This matter having been fully briefed, the Court resolves the pending motion for review.

## III. STANDARDS FOR DECISION

### A. Vaccine Act Claims

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2).

The special master's determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master's findings of fact are reviewed for clear error. *Id.* (citation omitted); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious."). The special master's discretionary rulings are reviewed for abuse of discretion. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In addition, a special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are "supported by substantial evidence." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citation omitted); *see also Burns by Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"). This "level of deference is especially apt in a case in which the medical evidence of causation is in dispute." *Hodges v. Sec'y of Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). And so, the Court will not substitute its judgment for that of the special master, "if the special master has considered all relevant factors and has made no clear

error of judgment." *Lonergan v. Sec'y of Dep't of Health & Human Servs.*, 27 Fed. Cl. 579, 580 (1993).

**B. Causation And Significant Aggravation**

Under the Vaccine Act, the Court must award compensation if a petitioner proves, by a preponderance of the evidence, all the elements set forth in 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table (the "Table"), or by proving causation-in-fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(i)-(ii); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And so, to receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either that: (1) petitioner suffered a "Table Injury" that corresponds to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, or (2) petitioner's illnesses were actually caused by a vaccine (a "non-Table Injury"). *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(i)-(ii), 300aa–14(a); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In addition, petitioner bears "a preponderance of the evidence" burden of proof. 42 U.S.C. § 300aa–13(a)(1)(A); *Althen*, 418 F.3d at 1278 (citing *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). And so, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2 (brackets existing) (citations omitted); *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (finding that mere conjecture or speculation is insufficient under a preponderance standard).

To establish a prima facie case for a non-Table injury, a petitioner must "prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface*, 165 F.3d at 1352. In addition, petitioner must prove by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal

relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. Medical or scientific certainty is not, however, required. *Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). And so, the Federal Circuit has held that all three of these elements "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

Specifically relevant to this dispute, the Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa–33(4). In non-Table cases, additional proof is necessary for a petitioner to prevail on a significant aggravation claim. 42 U.S.C. § 300aa-11(c)(1)(C).

Specifically, the Federal Circuit has held that to establish a prima facie case for the significant aggravation of a non-Table injury, a petitioner must show by preponderant proof: "(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to the vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) . . . a proximate temporal relationship between the vaccination and the significant aggravation." *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (quoting *Loving ex. rel. Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009)). The Federal Circuit has also held that "a petitioner in a [non-T]able case must show the vaccine actually caused the significant aggravation—not just that, accepting the Petitioner's medical theory as sound, the person's condition worsened within a medically-acceptable time frame." *Id.*

Lastly, if a petitioner establishes a prima facie case, the burden shifts to the Secretary to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *Shalala v. Whitecotton*, 514 U.S. 268, 270-71 (1995). But, regardless of whether the burden of proof ever shifts to the Secretary, the special

master may consider the evidence presented by the Secretary in determining whether petitioner has established a prima facie case. *See Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of Petitioner's evidence on a requisite element of Petitioner's case[-]in-chief.").

## IV. LEGAL ANALYSIS

In the motion for review, petitioner raises four objections to the special master's October 12, 2018, Decision denying his claim for compensation. First, petitioner argues that the special master committed legal error by "impermissibly raising the burden of proof" to show a direct link between HPV and MS/optic neuritis and requiring "confirmation or probability" of petitioner's medical theory in the medical literature. Pet. Mot. at 12-14. Second, petitioner argues that the special master erred by finding that petitioner had not proven a logical sequence to show that HPV significantly aggravated his optic neuritis symptoms. *Id.* at 16-17.

Third, petitioner argues that he has met his burden to show a significant aggravation of his MS/optic neuritis, because the special master noted in the October 12, 2018, Decision that petitioner would have met his burden of proof to show that a significant aggravation of his symptoms occurred within a medically-appropriate time frame. *Id.* at 17. Lastly, petitioner argues that the special master improperly disregarded the testimony and experience of his medical expert, Dr. Tornatore, in reaching the decision to deny his claim. *Id.* at 14-17. And so, petitioner requests that the Court either: (1) set aside the special master's October 12, 2018, Decision; (2) grant his claim for compensation; or (3) remand this matter to the special master. *Id.* at 2.

The Secretary counters in his response and opposition to petitioner's motion for review that the special master correctly determined that the evidentiary record in this matter does not support petitioner's claim for compensation. Resp't Resp. at 1-2. Specifically, the Secretary argues that the special master: (1) applied the proper legal burden to evaluate petitioner's claim;

(2) appropriately found that petitioner did not provide a logical explanation for how HPV significantly aggravated his MS/optic neuritis symptoms; and (3) appropriately found that petitioner did not experience an overall worsening of his MS/optic neuritis after receiving the third dose of HPV. *Id.* at 12-20. And so, the Secretary requests that the Court deny petitioner's motion for review and sustain the decision of the special master. *Id.* at 20.

For the reasons discussed below, the evidentiary record in this matter shows that the special master did not commit legal error, abuse his discretion, or act contrary to law, in reaching the decision to deny petitioner's Vaccine Act claim. And so, the Court (1) **DENIES** petitioner's motion for review of the special master's October 12, 2018, Decision and (2) **SUSTAINS** the decision of the special master.

### A. The Special Master Did Not Impose An Improper Burden Of Proof

As an initial matter, the record evidence shows that the special master did not commit legal error by imposing an impermissible burden of proof on petitioner in this case. The Court reviews the special master's determinations of law *de novo*. *Andreu*, 569 F.3d at 1373.

In his motion for review, petitioner argues that the special master impermissibly raised his burden of proof to show that HPV can cause, or significantly aggravate, MS/optic neuritis by requiring "confirmation or probability of the validity of the specific theory of causation in the medical literature." Pet. Mot. at 12; *see also Maciel*, 2018 WL 6259230, at *27. And so, while petitioner acknowledges that he did not provide "conclusive proof" that HPV can cause MS/optic neuritis, petitioner contends that he had no obligation to do so to prevail in this Vaccine Act case. Pet. Mot. at 12.

Petitioner's objection is not supported by the record evidence. In the October 12, 2018, Decision, the special master applied the legal framework for significant aggravation claims set forth in *Loving* and he reasonably determined that petitioner failed to offer preponderant evidence to support a claim that HPV significantly aggravated his MS/optic neuritis. *Maciel*, 2018 WL 6259230, at *25; *see also Loving*, 86 Fed. Cl. at 144. In reaching this determination, the special master acknowledged that petitioner "offer[ed] some reliable evidence in support of the 'can cause' element of his claim"—including recommendations from the National MS Society that vaccines not be administered during a MS relapse. *Maciel*, 2018 WL 6259230, at

*27. But, the special master determined that petitioner did not meet his burden of proof to demonstrate—with reliable scientific or medical evidence—that HPV can worsen the overall course of MS. *Id.*

The record evidence shows that the special master did not err in making this determination. First, the record evidence shows that the special master applied the correct legal standard in this case. As petitioner correctly observes, it is well-established that medical or scientific certainty is not required to prove causation in a Vaccine Act case. Pet. Mot. at 8; *see W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013). But, the Federal Circuit has held that petitioner must, nonetheless, present more than a possible causal link between a vaccine and injury; and the causal link must be based upon persuasive and reputable evidence. *Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 879 (Fed. Cir. 2013). And so, as the special master properly recognized, petitioner has "the ultimate burden of establishing [his] Vaccine Act claim overall with preponderant evidence." *Maciel*, 2018 WL 6259230, at *17. (emphasis removed)

Second, the record evidence makes clear that the special master appropriately considered petitioner's medical literature. In this regard, the record evidence shows that petitioner elected to submit eight medical articles to support his claim. Pet. Exs. 18-25; *see Maciel*, 2018 WL 6259230, at *5-10. The record evidence also shows that the special master reasonably concluded that petitioner's medical literature did not provide persuasive evidence to show a causal link between HPV and MS/optic neuritis. *Id.* at *27. As the special master observed during the entitlement hearing, none of petitioner's medical articles specifically address how HPV can cause, or exacerbate, MS. Tr. at 55:10-57:14; *see generally* Pet. Exs. 18-25. The special master also correctly observed in the October 12, 2018, Decision that the National MS Society study upon which petitioner relies does not show that HPV can exacerbate, or worsen, MS. *Maciel*, 2018 WL 6259230, at *27; Pet. Ex. 18 at 2-3.

Petitioner is correct in arguing that he had no obligation to submit medical literature in this case. But, once he elected to do so, it was appropriate for the special master to consider this evidence and to assess whether the medical literature supported petitioner's claim. Because the record evidence here shows that the special master reasonably determined that the medical

literature submitted by petitioner fails to support petitioner's medical theory, petitioner has not shown that the special master imposed an improper burden of proof in this case. [4]

### B. The Special Master Reasonably Found That Petitioner Failed To Explain How HPV Significantly Aggravated His Injury

Petitioner's objection that the special master abused his discretion by concluding that petitioner did not establish a logical sequence of cause and effect showing that HPV significantly aggravated his MS/optic neuritis is similarly unsubstantiated by the evidentiary record. *See* Pet. Mot. at 16. The Court reviews the special master's discretionary rulings for abuse of discretion and the special master's findings of fact for clear error. *Munn*, 970 F.2d at 870 n.10; *Andreu*, 569 F.3d at 1373; *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious.").

In his motion for review, petitioner argues that the testimony of his medical expert, Dr. Tornatore—coupled with evidence showing the reoccurrence of his MS/optic neuritis symptoms after receiving the third dose of HPV—is persuasive evidence showing that HPV significantly aggravated his MS/optic neuritis. Pet. Mot. at 16-17. But, as the special master observed in the October 12, 2018, Decision, the record evidence in this matter does not support petitioner's significant aggravation claim. *Maciel*, 2018 WL 6259230, at *25-28.

In the October 12, 2018, Decision, the special master found that HPV did not significantly aggravate petitioner's MS/optic neuritis because petitioner's post-vaccine symptoms constituted a single MS flare that predated the receipt of the third dose of HPV. *Id.* at * 25. Notably, the special master found that petitioner's optic neuritis had not completely resolved prior to the date on which petitioner received the third dose of HPV. *Id*. In addition,

[4] It is also important to note that the special master's determination that petitioner failed to show that HPV can cause, or significantly aggravate, MS/optic neuritis was not based solely upon petitioner's medical literature. The record evidence shows that special master considered, among other things, the testimony of petitioner's expert. *Maciel v. Sec'y of Health & Human Servs.*, No. 15-362V, 2018 WL 6259230, at *27 (Fed. Cl. Spec. Mstr. Oct. 12, 2018). In this regard, the special master found that "Dr. Tornatore did not relate in his testimony particularized observations from his own medical experience that would render [the contention that HPV can cause a worsening of MS] plausible." *Id.*

the special master observed that the Secretary persuasively established that optic neuritis does not commonly resolve quickly, especially in pediatric patients. *Id*. And so, the special master reasonably concluded that the symptoms that petitioner experienced both before and after receiving the third dose of HPV "were all a part of a single flare" and not evidence of a significant aggravation of petitioner's MS/optic neuritis symptoms, based upon the evidence presented in this case. *Id*.[5]

Petitioner's claim that Dr. Tornatore's expert testimony establishes a logical sequence in this case is also not substantiated by the record evidence. During the entitlement hearing, Dr. Tornatore testified that the sudden increase in eosinophils in petitioner's bloodstream following the receipt of the third dose of HPV is an indication of a reaction to a vaccine. Tr. at 23:24-24:3; *see also id.* 55:18-56:2. But, the record evidence shows that none of petitioner's treating physicians diagnosed petitioner with eosinophilia in 2014, nor did they find petitioner's elevated eosinophil levels to be abnormal at that time. Pet. Ex. 14 at 63-70. Given this evidence, petitioner has not shown that the special master erred in finding that petitioner failed to show how HPV could significantly aggravated his MS/optic neuritis in this case. *Munn*, 970 F.2d at 870.

### C. The Special Master Reasonably Concluded That Petitioner Did Not Experience An Overall Worsening Of His Symptoms

The evidentiary record in this matter also makes clear that the special master did not err by concluding that petitioner failed to show a worsening of his symptoms after receiving HPV, as petitioner suggests. Pet. Mot. at 17-18. In his motion for review, petitioner argues that he has shown a worsening of his symptoms after receiving the third dose of HPV, because Dr. Tornatore testified that petitioner's MS course changed significantly after receiving HPV. *Id.* Petitioner also argues that the special master improperly disregarded Dr. Tornatore's testimony

[5] When questioned by the Secretary during cross-examination, petitioner acknowledged that he knew of no medical literature that supports his theory that HPV can cause, or significantly aggravate, MS/optic neuritis. Tr. at 29:18-29:20.

in this regard in determining that petitioner did not establish a worsening of his MS/optic neuritis symptoms.[6] *See Id.* at 17-18. Petitioner's objections lack support in the evidentiary record.

It is well-established that to establish a prima facie case for the significant aggravation of a non-Table injury, a petitioner must show, among other things, that his current condition constitutes a "significant aggravation" of his condition prior to the vaccination within the meaning of the Vaccine Act. *W.C.*, 704 F.3d at 1357 (quoting *Loving*, 86 Fed. Cl. at 144); *see also Williams v. Sec'y of Health & Human Servs.*, No. 04-1725V, 2007 WL 2775190, at *26 (Fed. Cl. Spec. Mstr. Sept. 11, 2007). The Federal Circuit has also held that "a petitioner in a [non-T]able case must show the vaccine actually caused the significant aggravation—not just that, accepting the Petitioner's medical theory as sound, the person's condition worsened within a medically-acceptable time frame." *W.C.*, 704 F.3d at 1357. And so, petitioner must show that he experienced a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health," after receiving the third dose of HPV. 42 U.S.C. § 300aa–33(4).[7]

The record evidence in this case makes clear that the special master reasonably concluded that petitioner has not shown a worsening of his symptoms after receiving the third dose of HPV. In the October 12, 2018, Decision, the special master considered whether the third dose of HPV made the petitioner worse than he would have been, but for receiving this vaccination. *Maciel*, 2018 WL 6259230, at *26. In this regard, the special master found that the medical record did not suggest that petitioner's MS/optic neuritis was "notably worse" than what would be expected

[6] Petitioner also argues that the special master impermissibly required that he show that his MS/optic neuritis symptoms were severe. Pet. Mot. at 17-18. But, a review of the October 12, 2018, Decision and the record evidence makes clear that the special master did not require petitioner to show severity. *See generally Maciel v. Sec'y of Health & Human Servs.*, 2018 WL 6259230 (Fed. Cl. Spec. Mstr. Oct. 12, 2018).

[7] This Court has at times considered whether a petitioner was literally worse after receiving a vaccine to determine whether there has been a post-vaccination worsening of a pre-existing condition. *See e.g.*, *Williams*, 2007 WL 2775190, at *27. The Court has also considered whether the vaccine made the petitioner worse than he would have been, but for the vaccination, to make this determination. *See, e.g.*, *Faoro v. Sec'y of Health & Human Servs.*, No. 10-704V, 2016 WL 675491, at *27 (Fed. Cl. Spec. Mstr. Jan. 29, 2016). And so, under either analysis, the critical issue for the Court to consider is "whether the change for the worse . . . was aggravation or a natural progression" of the petitioner's injury. *Hennessey v. Sec'y of Health & Human Servs.*, No. 01-190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009).

for an individual suffering from MS who received no vaccine. *Id*. The special master's finding is supported by the record evidence in this case, which shows that petitioner was already in the "intermittent vector" of his MS when he received the third dose of HPV on March 6, 2014. *See Maciel*, 2018 WL 6259230, at *26; Pet. Ex. 14 at 114. The record evidence also supports the special master's finding because the evidence shows that petitioner's MS/optic neuritis symptoms were not notably worse than what other MS patients would have experienced without having received a vaccine. *See* Tr. at 165:13-165:14; *see also Maciel*, 2018 WL 6259230, at *26. And so, given the evidentiary record, the special master reasonably concluded that "the record in this case is simply inconsistent with [p]etitioner's contention that he experienced a serious deterioration of his MS due to vaccination." *Maciel*, 2018 WL 6259230, at *26.[8]

**D. The Special Master Appropriately Weighed The Testimony Of Dr. Tornatore**

As a final matter, the record evidence also shows that the special master appropriately weighed and considered the testimony of petitioner's expert, Dr. Tornatore. The Court will not disturb the special master's findings regarding the credibility of Dr. Tornatore so long as they are "supported by substantial evidence." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citation omitted); *see also Burns by Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master").

In this case, the record evidence shows that the special master appropriately assessed and considered the testimony of Dr. Tornatore in resolving petitioner's Vaccine Act claim. Specifically, the record evidence shows that the special master acknowledged in the October 12, 2018, Decision that Dr. Tornatore was a competent and credible witness with expertise on the topic of MS. *Maciel*, 2018 WL 6259230, at *28. In this regard, the special master specifically

[8] The special master's determination that petitioner established that any significant aggravation of his symptoms occurred within a medically-appropriate time frame does not revive petitioner's Vaccine Act claim. While the special master determined that "the timing in which the aggravation is alleged to have occurred [in this case] was medically appropriate given [p]etitioner's theory," the special master also made clear that he did not find petitioner's theory to be plausible, "given the lack of reliable science supporting it." *Maciel v. Sec'y of Health & Human Servs.*, 2018 WL 6259230, at *24, n. 29 (Fed. Cl. Spec. Mstr. Oct. 12, 2018).

states in the October 12, 2018, Decision that "[o]verall I found [Dr. Tornatore] to be a competent and credible expert, with more than sufficient expertise on the topic of MS and interpretation of the radiologic evidence relevant to it to opine in this case." *Id.* But, the special master also observed in the October 12, 2018, Decision that Dr. Tornatore's "professional focus is not on immunologic matters." *Id.* Petitioner does not dispute the special master's findings in this regard. Pet. Mot. 14-16.

While petitioner correctly observes that the special master erred by identifying Dr. Tornatore as the vice chairman of the Department of Neurology at MedStar Georgetown University Hospital in the October 12, 2018, Decision, petitioner does not explain how this error impacted the special master's analysis of this Vaccine Act matter. Pet. Mot. at 15; *see also Maciel*, 2018 WL 6259230, at *5. As discussed above, the record evidence shows that the special master found Dr. Tornatore to be an expert regarding MS, and the record evidence also shows that the special master appropriately considered and weighed Dr. Tornatore's expert testimony. Given this, the special master reasonably concluded that Dr. Tornatore's "overall credibility and expertise on the topic of MS was not enough to imbue [the sub-component of his testimony regarding how the innate immunologic properties of a vaccine could produce a MS flare] with the evidentiary heft needed to outweigh [the Secretary's] more robust, literature-supported contentions that HPV specifically is *unlikely* to contribute to the processes resulting in MS, cause a damaging flare, or worsen an existing flare to the degree necessary to significantly aggravate a course of MS." *Id.* (emphasis in original).

Because, petitioner simply has not shown that the special master improperly weighed or disregarded the testimony of Dr. Tornatore, the Court must reject petitioner's final objection to the special master's decision.

## V. CONCLUSION

In sum, the evidentiary record in this matter shows that the special master did not abuse his discretion, or act contrary to law, in finding that petitioner has not established that HPV caused, or significantly aggravated, his MS/optic neuritis. And so, for the forgoing reasons, the Court:

(1) **DENIES** petitioner's motion for review of the special master's October 12, 2018, Decision; and

(2) **SUSTAINS** the decision of the special master.

The Clerk shall enter judgment accordingly.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential, or sensitive personally-identifiable information that should be protected from disclosure. And so, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall **FILE** a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed redaction, on or before by **May 1, 2019**.

**IT IS SO ORDERED.**

s/Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
Judge